



09/10/864
PCT/AU97/00259

REC'D 13 MAY 1997

WIPO PCT

Patent Office
Canberra

I, DAVID DANIEL CLARKE, ASSISTANT DIRECTOR PATENT SERVICES, hereby certify that the annexed are true copies of the provisional specification and drawing(s) as filed on 30 April 1996 in connection with Application No. PN 9597 for a patent by MICHAEL SHANE CAVANAGH filed on 30 April 1996.

I further certify that pursuant to the provisions of Section 38(1) of the Patents Act 1990 a complete specification was filed on 29 April 1997 and it is an associated application to Provisional Application No. PN 9597 and has been allocated No. 19948/97.

I further certify that the annexed documents are not, as yet, open to public inspection.

PRIORITY DOCUMENT

WITNESS my hand this Seventh
day of May 1997


DAVID DANIEL CLARKE
ASSISTANT DIRECTOR PATENT SERVICES



21

protection at all to the users against accidental injury from the scalpel blade. Injury from scalpel blades carry the possibility of an individual contracting a serious or fatal disease and this tray is designed to minimise this risk.

SEE FIG 2 ← The multiple scalpel blade and handle tray is a purpose built tray designed for the storage of more than one scalpel blade and handle combination on the instrument trolley of a scrub nurse in an operating theatre. The tray provide recessed areas for the scalpel blades themselves and a raised section underneath the handles allowing the user to safely grasp the handle and remove or replace the scalpel blade and its handle into the tray. The recessed area for the scalpel blade minimises the chance of the user accidentally injuring themselves on the sharp scalpel blade. A raised edge located behind the blades handle, combined with the set length of the recessed area for the blade, gives the scalpel blade and its handle minimal fore and aft movement thereby not allowing the sharp blade to slide out of the recessed area and come into contact with the users fingers. This provides safety for the user when they are grasping the handle to remove the blades from the tray. A raised section underneath the blades handle allows the user sufficient room to enable them to grasp the handle by elevating the blades handle above the main baseplate section/

The tray is designed to store up to four blade and their handles, two long and two short handles fitted with a variety of scalpel blades. The unit also features a recessed area for the safe storage of long Veress needles. These needles are long hypodermic type needles used for the introduction of gas into the abdominal cavity for visualisation of the abdominal and pelvic cavities during surgical operations. The tray will prove useful where more than one scalpel blade is used during a surgical operation as it provides a safe means of storing these sharp scalpel blades when they are not in use. The majority of surgical operations require the use of more than one scalpel blade, The current method for storing blades and their handles on the instrument trolley of scrub nurses is to simply place them into an open kidney shaped dish or to leave them sitting loosely on the sterile cloth drape which covers the instrument trolley. Removing the blade and its handle from these kidney dishes involves a risk of being cut by the blade and storing them loosely on the drapes not only involves the same risk but also carries the risk of the sharp blade penetrating the cotton trolley drape and rendering the blade tip unsterile. This would then render the cloth trolley drape unsterile as well and would also put the patient at risk of contracting an infection. The tray is of a sufficiently low and squarish design to give it stability on an instrument trolley and thereby reduce the risk of its contents falling out and causing injury.

SEE FIG 3 → The suture needle tray is a plastic tray designed for the safer transfer of surgical suturing needles and their threaded suture material during an operative procedure such as occurs in an operating theatre. The tray features three distinct sections and is rectangular in shape. A raised lip around the perimeter of the tray helps contain the needle holding instrument housed within it. The three sections of the tray are continuos with each other and together form the baseplate of the tray. The three sections are arranged in tiered arrangement to facilitate the trays safety features. One end of the tray features a half round dished area into which the suture needle and its attached suture material are housed. Surgical suturing needles are half round in shape and this section is designed as a recessed area in which the needles are housed to avoid anyone coming into contact with the sharp needle. This recessed area also houses the

PROVISIONAL
PN 9597

The scalpel blade and handle tray, the multiple scalpel blade and handle tray and surgical suture needle tray are all plastic trays designed for the safer handling of scalpel blades and suture needles used in surgical operations and procedures in the medical and/or hospital and related fields. Each tray is purpose built and is designed to suit both the type of sharp being used and by the way the sharps are used by the operator. All three trays feature one basic concept and that is to house the sharp scalpel blade or suture needle in a recessed area where it can not accidentally come into contact with the users fingers.

The scalpel blade and handle tray, see Fig 1, is a tray designed specifically for the transfer of a scalpel blade and handle combination, from one person to another, such as occurs during a surgical operation between a surgeon and a scrub nurse. The unique feature of the tray is in its ability to protect the users fingers from accidental injury during blade/handle removal from the tray. This is achieved by two features. Firstly, the blade and its handle are housed in a recessed gutter in the base of the tray. This recessed gutter is slightly wider and slightly higher than a scalpel blade and handle combination and together with the trays downwards sloping sidewalls, does not permit the fingers of the user to touch the sharp scalpel blade.

The second feature is one sideways half round vertical recess in each of the trays downward sloping sidewalls. These sidewall recesses are located at the centre of the trays length and they, together with a slightly deeper recessed gutter area in the base at this point give the user the only access point to grasp the blades handle. To avoid the scalpel blade and its handle from sliding back and forward in the recessed gutter too far and thereby possibly positioning the sharp scalpel blade in the centre of the tray where the recesses for the users fingers are located, the total length of the tray has been designed so that the recessed main gutter is long enough to accept all available blade and handle combinations whilst providing minimal fore and aft movement at the same time. This therefore means that the shortest of the available blade and handle combinations, which will of course have the largest fore and aft movement in the gutter, will still have its sharp blade positioned outside the centre recessed area dedicated to the users fingers. Accidental injury is therefore minimised.

Another feature of the tray is its downwards sloping side and end walls. These in combination with the width of the top of the tray mean that the user requires less precision in replacing the blade and its handle into the tray than if they had to place the blade and its handle into a designated recessed area.

The downward sloping side and end walls also help direct the scalpel blade and its handle positively toward the recessed gutter in the trays base. As scalpel blades are wider than they are thick and the same is true of blade handles, the scalpel blade and its handle will always come to rest in a flat position in the recessed gutter in the base of the tray. This ensures that the sharp scalpel blade is always below the upper edge of the recessed gutter and therefore inaccessible to anyone's fingers. The trays low and wide design will give it a low centre of gravity thus giving it stability on uneven surfaces such as when placed on a patients person during a surgical procedure or operation.

The tray is designed to replace the current trays used for the transferring of scalpel blades and their handles which is an open topped kidney shaped dish which gives no

3/

suture material. The centre section of the basipetal is a section which slopes downwards at an angle toward the recessed area for the needle and thread. This section also has incorporated into it a vee shaped sub-section with the apex of the sub-section located at the lip of the dished recessed area for the needle and thread. The other end of the tray features a flat section which is slightly higher in elevation than the middle sloping and dished recess areas.

When a fully loaded needle holder is placed into the tray, which are basically shaped like a pair of long fine pliers with a handle locking mechanism, the following situation occurs. Firstly the suture needle sits below the middle sloping section in a dished recessed area. This provides increased protection for the users from a needle stick injury. Secondly, the width of the recessed area for the needle, in terms of tray length, provides as little as possible fore and aft movement as possible thus offering stability for the needle holder and its attached suture needle.

Thirdly the vee section in the middle sloping section of the baseplate allows the needle holders jaws and part of its body to sit lower down in comparison to the height of the rest of the sloping middle baseplate. This means that the actual tip or sharp point of the suture needle is below the middle baseplate section and therefore minimises the risk of a persons fingers accidentally coming into contact with the sharp needle.

As the middle section of the baseplate is sloping downwards toward the recessed area for the needle it means that the end of the needle holder that the user will grasp will sit higher than the flat section of the baseplate that is directly underneath it. This then allows the users fingers sufficient room to insert their fingers into the finger grips of the needle holder and remove it for use. The unit could be manufactured to suit a variety of needle holder sizes. The recessed area which houses the suture needle also houses the suture material attached to the needle. This is important from a sterility point of view. Suture materials vary in length and in elasticity and some modern materials are very loose and fall freely to their full length under gravity. In an operating theatre anything that falls below the scrub nurses waist level is deemed to be unsterile and therefore endangers the patient of contracting an intra-operative infection. Often during current methods of needle holder and suture transfer between surgeon and scrub nurse this very situation occurs. Storing all of the suture material in the dished recessed area of the tray avoids this problem. The tray also provides another form of protection for the patient and that is against needle stick injury. Often when the scrub nurse is busy the surgeon will place a needle holder with a suture needle loaded onto it onto the drapes covering the patient when they have finished and this can then penetrate the drapes and injure the patient. The personal transfer of a loaded needle holder from one person to another, which is what happens on the theatre industry at the moment, also carries a high risk of needle stick injury. The suture tray will help to minimise all of the risks. The low and rectangular design of the tray will give it sufficient stability when placed on a patients person during an operation.

The straight needle holding tray, see Fig 4, is a purpose built tray designed for the safer transfer of straight surgical suture needles during a surgical operation or procedure. These particular needles are hand held by the surgeon and are passed from the scrub nurses to the surgeon by hand. These straight needles are only used for suturing the final layer, that is the skin, during an operation. The physical transfer of these type of

4/

needles between members of a surgical team involves an extremely high risk of needle stick injury. The tray is designed to eliminate the need for the physical transfer of the straight needle by scrub team members from one to another.

The tray has four main features which provide a safer method of needle transfer. The tray is a rectangular shape and is attached to an open boxed section on one end. The base of the tray extends out sideways, being wider than the above rectangular section and provides wings on either side of the tray. The top of the tray, which is the rectangular area, has on its top a long fine recessed gutter sufficient to accept the long fine straight needle. This recessed gutter is shorter than the full length of the needle which allows the blunt end of the needle to protrude far enough at the other end of the recessed gutter for the user to grasp the needle and remove it for usage. This blunt end of the needle to which the suture material is attached sits out over the open boxed section which is a continuation of the rectangular section into which the recessed gutter for the needle is located. This open boxed section serves two purposes. Firstly it houses the suture material so it does not become unsterile during transfer and secondly it gives the users fingers sufficient room to be able to grasp the blunt end of the needle. As straight suture needles are very fine they are also very light in weight. To ensure that the light needle does not become dislodged during transfer, a small magnet is located in the plastic immediately underneath the recessed gutter for the needle. Even if the tray were overturned the needle would not fall out.

The wide baseplate which features wings out either side serves two purposes. Firstly it gives the tray the required stability for placing on a patient during an operation and secondly it provides a sliding drawer type of arrangement with the underside of the suture needle tray described in Fig 3. A handle on the outside of the open boxed section allows it to be easily removed from the underside of the suture needle tray.

Therefore the four safety features of the tray are; 1] A recessed gutter to house the sharp straight needle and avoid injury to the staff using it. 2] A magnet underneath the recessed gutter to prevent dislodgment of the needle from the tray. 3] A boxed section for the storage of the needles suture material and to provide an access point to grasp the needle safely. 4] A wide baseplate featuring wings which give the tray the required stability for use in surgical operation.

All of the four trays described will be made from autoclavable plastic and will feature sufficient steam ventilation holes for the purpose.

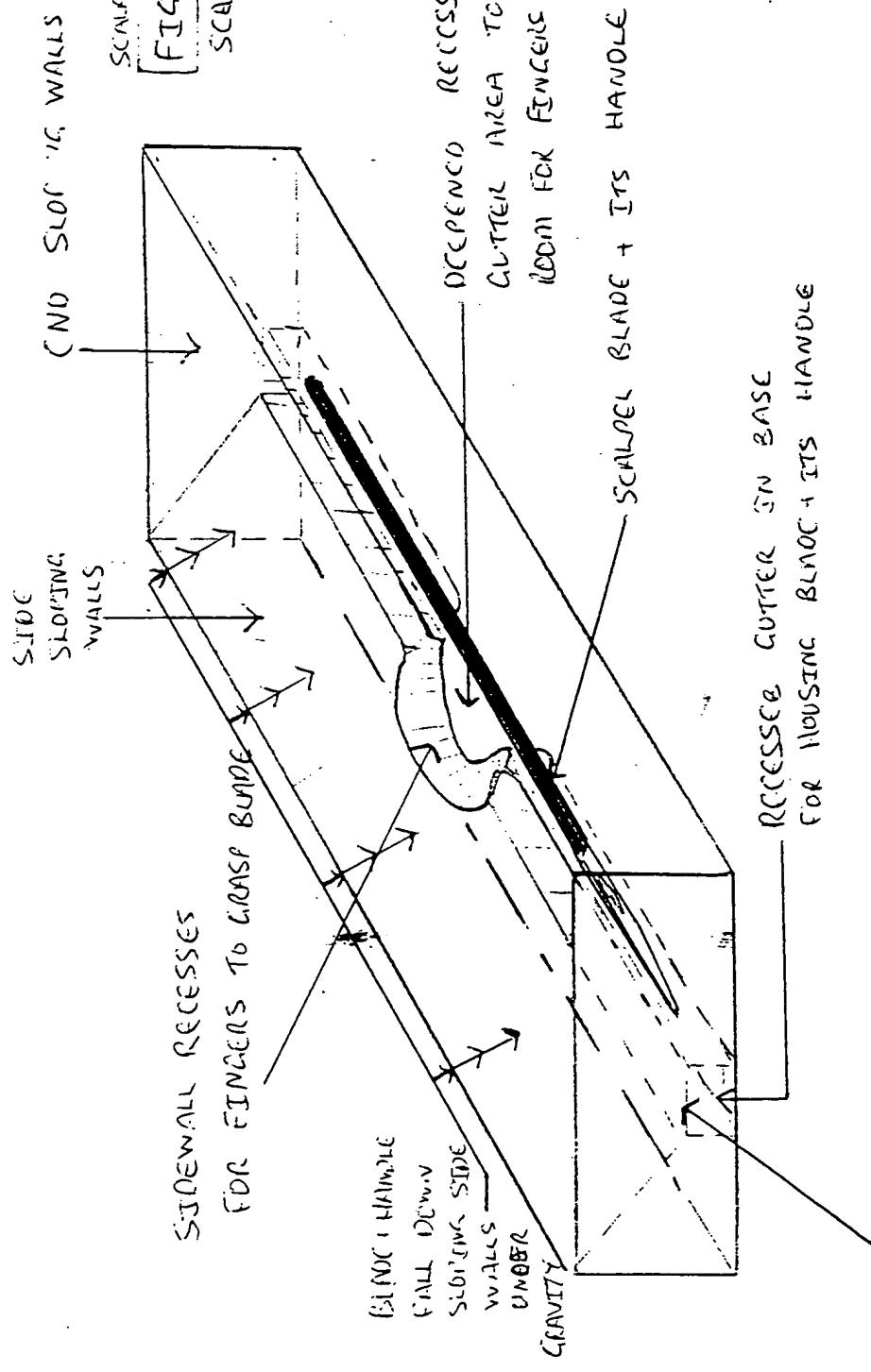
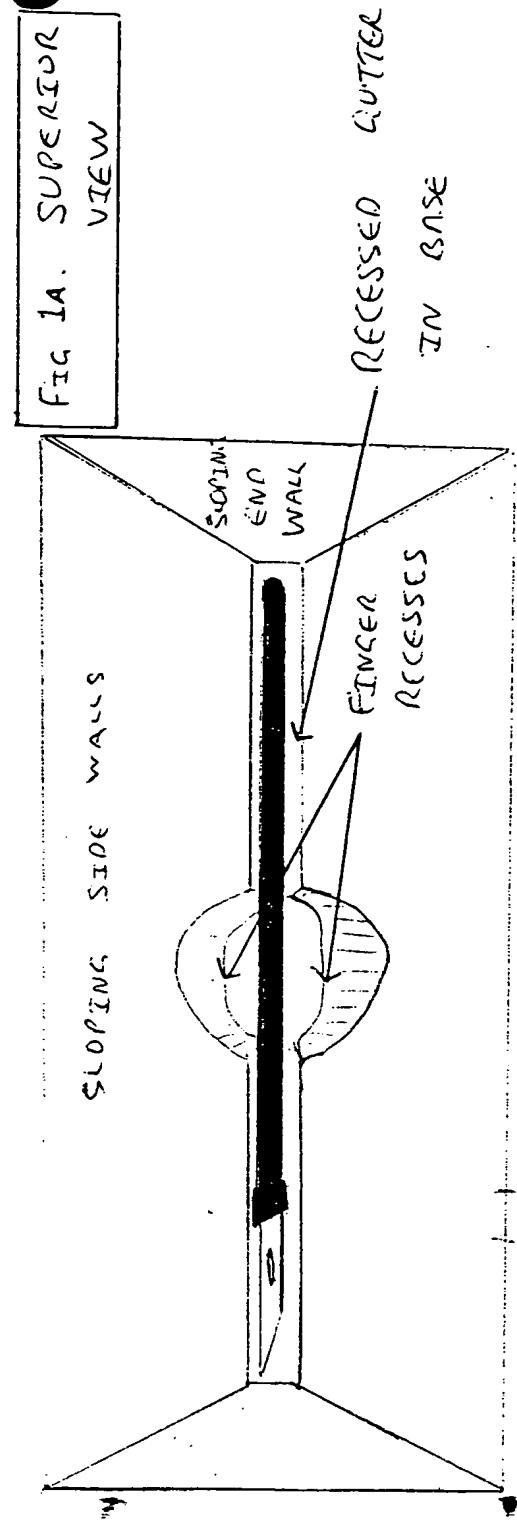


FIG. 1. OBlique VIEW
SCARFEL + RUMFORD + HANRÉE
SCARFEL + RUMFORD + HANRÉE
SCARFEL + RUMFORD + HANRÉE



2. MULTIPLE
BLADE + HANDLE ~~HOLDER~~ TRAY

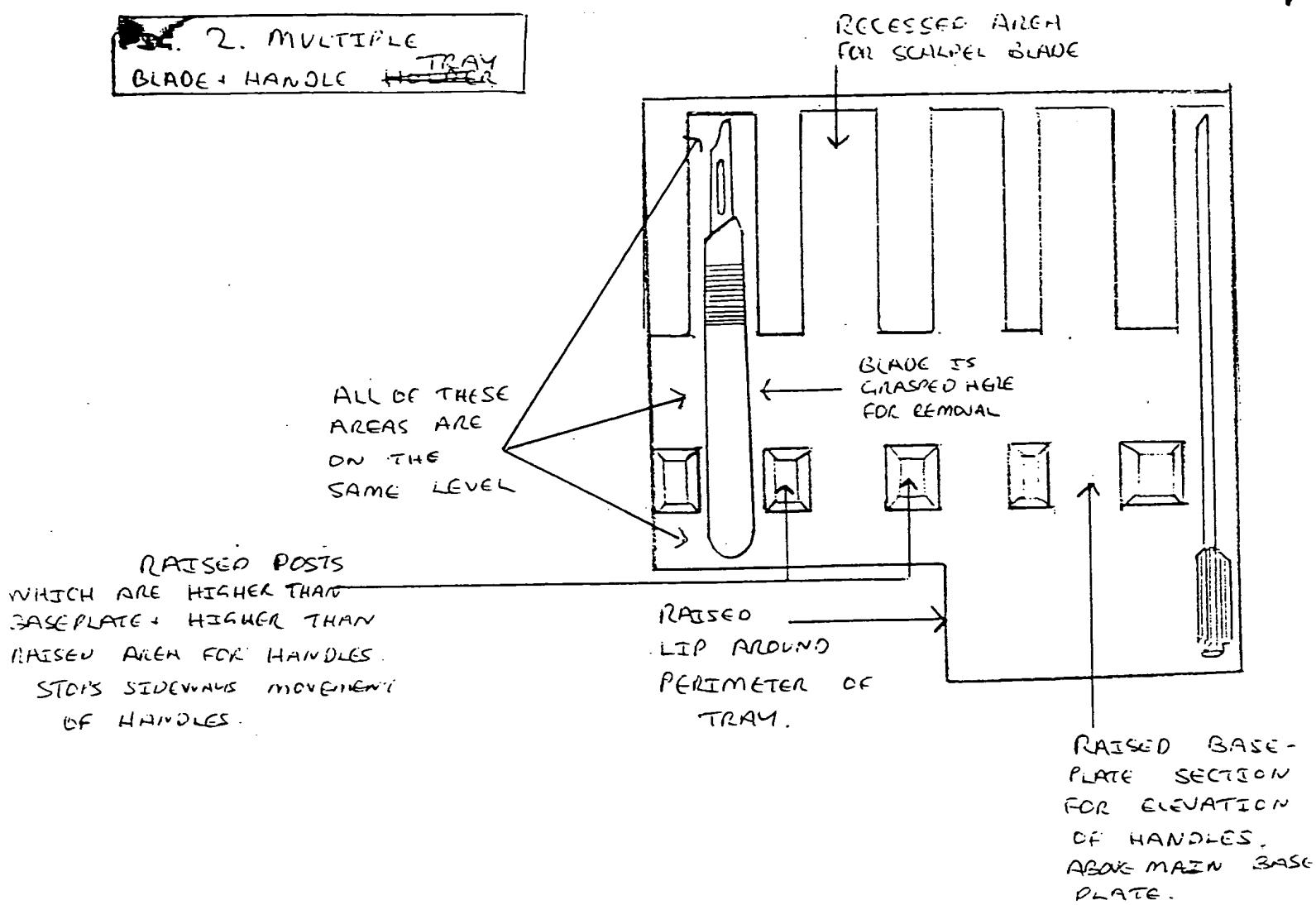
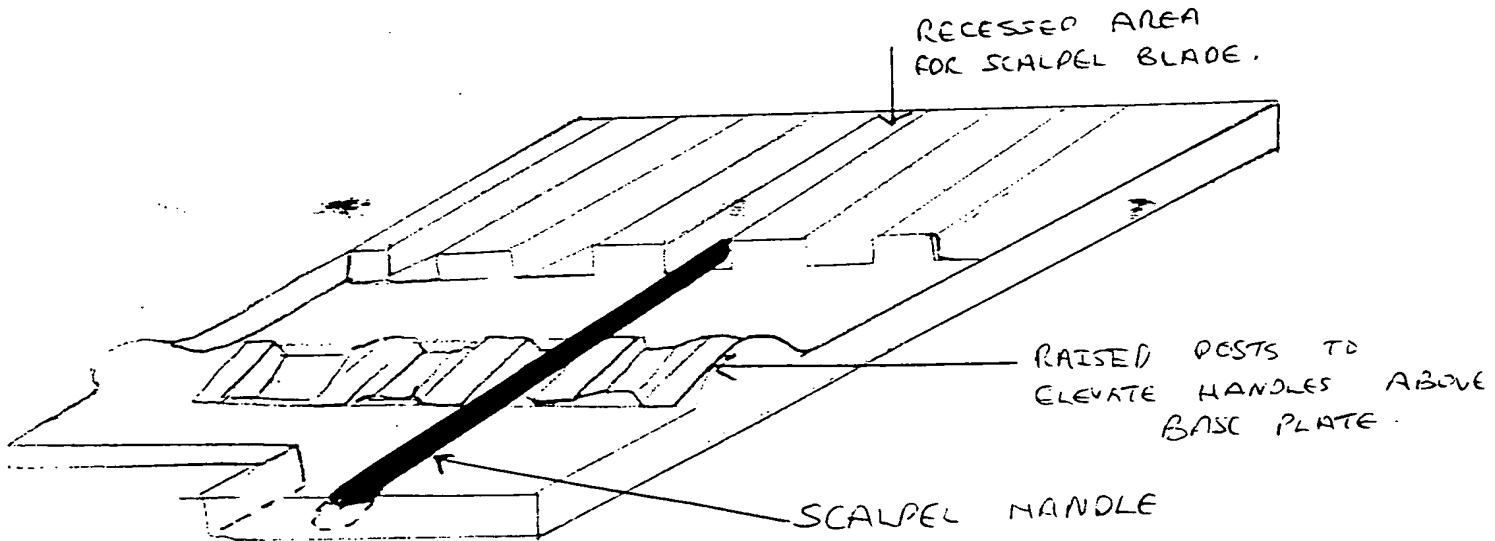


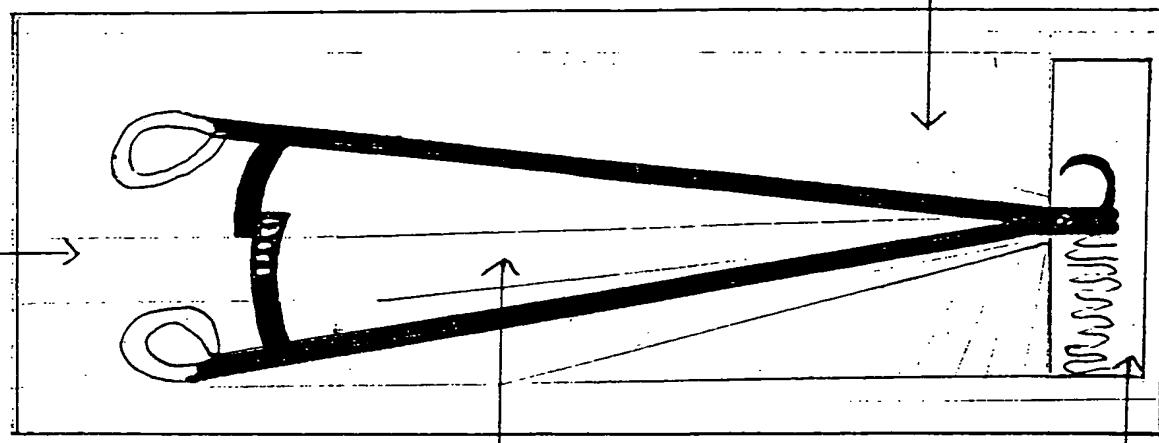
FIG 2: OBLIQUE VIEW



SUTURE NEEDLE TRAY - SUPERIOR VIEW

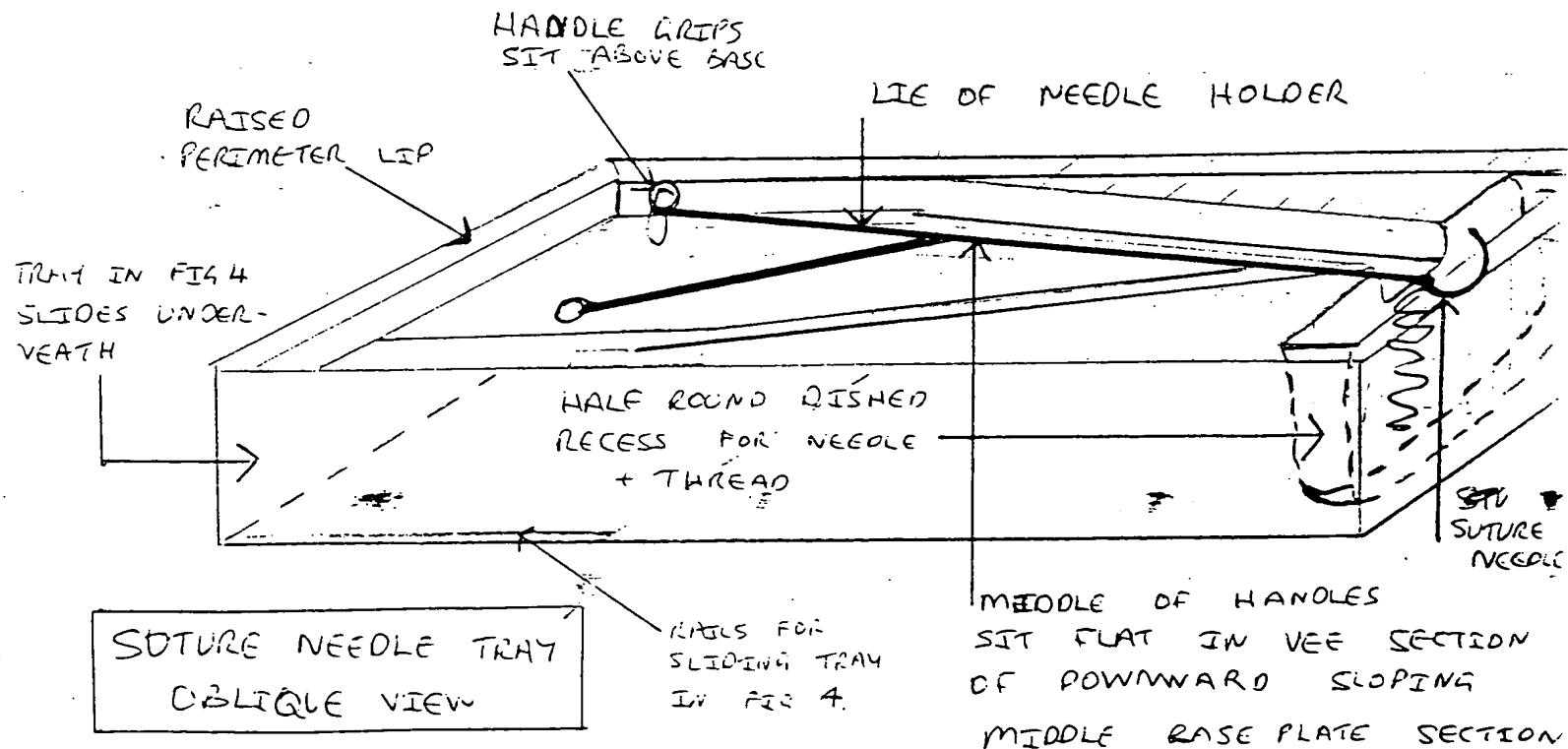
DEEPER SLOPING
SIDEWALLS

FLAT
ELEVATED
BASE
SECTION



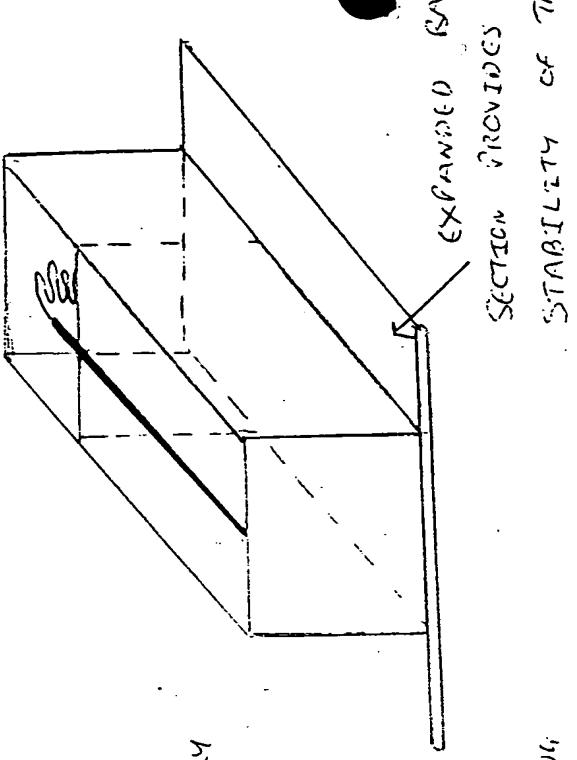
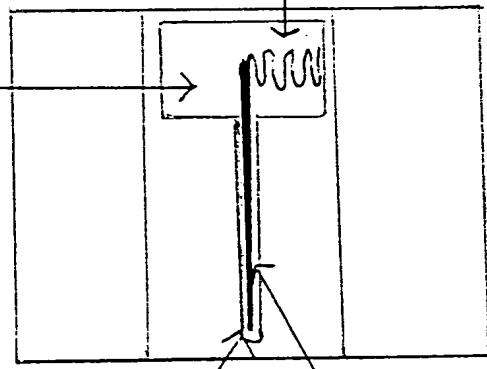
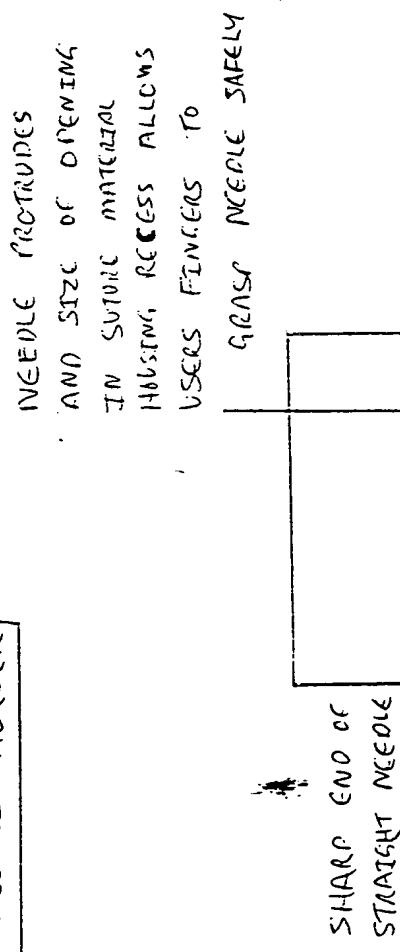
SLOPING DOWNWARDS
MIDDLE BASE
SECTION IS THE
VEE SECTION WHICH
STABILIZES HOLDER.

HALF ROUND
DISHED
RECESSED AREA
FOR NEEDLE
& THREAD.



STRAIGHT NEEDLE HOLE

FIG. 4



SUPERIOR VIEW

STRAIGHT NEEDLE

PROCESSED SURFACE

CO. HOLLOWING

STRAIGHT NEEDLE

SHARP END OF STRAIGHT NEEDLE

SQUARE ACCESSORY BOX FOR STORING NEEDLES THEREIN

SECTION PROVING
STABILITY OF TRAIL
EXPANDED GASKET

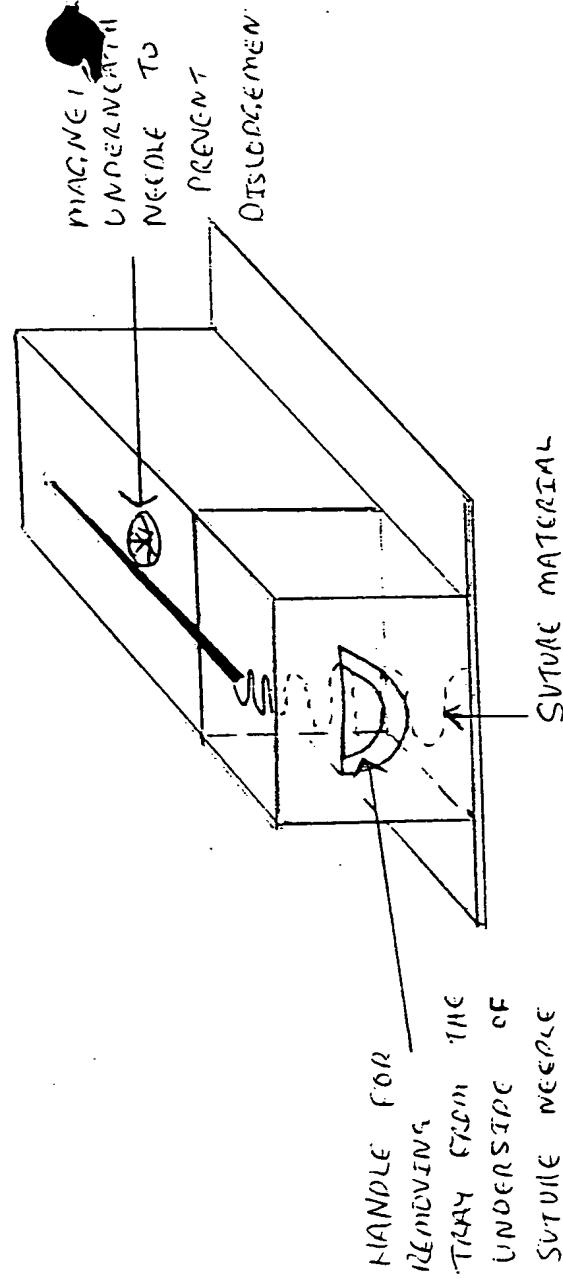


FIG. 5 IN FIG. 3